UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 MOTIONS	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR RECONSIDERATION OF THE COURT'S ORDER OF AUGUST 26, 2016 LIMITING OR EXCLUDING THE EXPERT OPINIONS OF DR. JERRY BLAIVAS, M.D.

Now come Plaintiffs seeking reconsideration of this Court's order of August 26, 2016 limiting or excluding the expert medical opinions of Dr. Jerry Blaivas, M.D. ("Dr. Blaivas"), in Wave 1 of the litigation pending against Defendant Ethicon, Inc. ("Ethicon") before this Court. *See In re Ethicon Pelvic Repair Systems Product Liability Litig.*, MDL No. 2327, 2016 WL 4500767 (S.D.W. Va. August 26, 2016) ("Order"). Plaintiffs say the following:

I. INTRODUCTION

Fully recognizing that motions for reconsideration are not to be requested simply as "do-overs" or without careful regard for the Court's limited resources, Plaintiffs now move that sufficient reasons exist in law and in fact for this Court to reconsider its Order excluding Dr. Blaivas's expert opinions. The reasons include the fact that to a significant degree, Ethicon misconstrues the scientific support for Dr. Blaivas's opinions. This is particularly the case for his opinions pertaining to the safety and efficacy rates of Ethicon's transvaginal mesh products

including the entire family of TVT mesh slings ("TVT devices"). Unfortunately, Ethicon's misinterpretation led it to posit arguments to the Court that support the Court's Order but are, in fact, without merit. As such, it is fundamentally unfair for Dr. Blaivas's opinions regarding safety and efficacy rates to be excluded, thereby also resulting in the Wave 1 Plaintiffs lacking vital support for their cases. Second, Dr. Blaivas supplemented his expert report pursuant to Federal Rule of Civil Procedure ("Rule") 26(e)(2) on October 17, 2016 with very recent scientific literature that was not available to Dr. Blaivas or to the Plaintiffs when he originally proffered his opinions relevant to the Wave 1 litigants. Thus, there is now additional evidence to support Dr. Blaivas's opinions. Plaintiffs move this Court to reconsider its earlier Order on this basis as well.

II. LEGAL STANDARD

The Fourth Circuit has held that Rule 54(b) governs a motion for reconsideration of a *Daubert* motion. *See Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469-70 (4th Cir. 1991); *see also Bragg v. Robertson*, 183 FRD 494, 495-96 (S.D.W. Va. 1998)(courts have the power to amend interlocutory orders "to achieve complete justice."). Rule 54(b) says in relevant part, "any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54. By any measure, a *Daubert* motion, such as the one decided by this Court's earlier Order, is precisely the type of decision not adjudicating all of the claims of the parties in this action that is contemplated by Rule 54.

Rule 54 cannot and does not serve as a mechanism to request a "do-over" by a court - - even if the court's earlier decision was wrong. *See In re Ethicon, Inc.*, Nos. 2:12-MD-02327, 2327,

2014 WL 457544 at *1 (S.D.W. Va. February 3, 2014)("Notwithstanding that precept, [i.e. that Rule 54(b) applies] it is improper to file a motion for reconsideration simply to ask the Court to rethink what the Court had already thought through - - rightly or wrongly.")(internal citation and quotation omitted.). However, there are certain situations in which the Rules allow courts to reconsider previous orders as the Plaintiffs request here. The Fourth Circuit recognizes three grounds for amending a judgment:

> '(1) to accommodate an intervening change in controlling law;
> (2) to account for new evidence not available at trial, or
> (3) to correct a clear error of law or prevent manifest injustice.'

Id. (quoting *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998))(applying the same standards required by Rule 59(e) and 60(b) to a Rule 54(b) determination.).

III. LEGAL ARGUMENT

While Plaintiffs are aware that motions for reconsideration are considered "extraordinary remed[ies] which should be used sparingly," *see In re Ethicon*, 2014 WL 457544 at *1, they move that the facts justify this Court granting one here for reasons of the following.

A. ETHICON MISLED THIS COURT REGARDING DR. BLAIVAS'S OPINIONS ON EFFICACY AND SAFETY RATES, CAUSING THE COURT TO EXCLUDE HIS OPINIONS BASED ON MISUNDERSTANDING

In the Order, this Court excluded Dr. Blaivas's opinions about safety and efficacy rates, based largely on Ethicon's misunderstanding of, if not outright misstatements about, Dr. Blaivas's supporting data. *See In re Ethicon*, 2016 WL 4500767 at *4 (the Court excluding Dr. Blaivas's opinions on safety and efficacy rates, finding that they were grounded in identical data the Court previously excluded in *Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 721 (S.D.W. Va. 2014)).

In making its argument in Wave 1,[1] Ethicon cited primarily to the deposition testimony that Dr. Blaivas proffered on September 17, 2015.[2] (Eth. Br., 3-7.) Unfortunately, Ethicon misinterpreted both Dr. Blaivas's testimony and the data in his expert report pertinent to safety and efficacy rates. For example, Ethicon contended that Dr. Blaivas's complication rate opinion was unreliable because 1) he previously testified at a 2014 trial (*see Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 721 (S.D.W. Va. 2014) that he could not offer testimony about complication rates (Eth. Br., 4) and 2) because his deposition was ostensibly vague and unsupported by the scientific literature. (*Id*., 3-7.)

Regarding *Huskey*, Ethicon failed to ask any questions, whatsoever, regarding Dr. Blaivas's testimony at that 2014 trial during his 2015 deposition. And yet, Ethicon still argued that Dr. Blaivas's opinions on complication rates relevant to the Wave 1 Plaintiffs' cases in 2016 were unsupported simply because the Court held them to be so during the 2014 *Huskey* trial. (*Id*., 4.) Had Ethicon bothered to ask, it would easily have discovered that Dr. Blaivas acquired new support for his opinions after Mrs. Huskey's trial in the form of new research. Dr. Blaivas testified as such at his deposition pertaining to the TVT-Exact device[3] on August 29, 2016 ("2016 deposition"):[4]

> Q. So, since you testified in Mrs. Huskey's case in the summer of 2014, have you done additional work that you rely on as the basis for your current

[1] Ethicon moved to exclude Dr. Blaivas's opinions in Wave 1 in its Motion and Memorandum in Support of Its Motion to Exclude Certain Opinions of [Dr. Blaivas] filed with the Court April 21, 2016 ("Ethicon Brief"). Future citations to the Ethicon Brief will be in the form (Eth. Br., ___.)

[2] Future references to the deposition of September 17, 2015 will be in the form "2015 deposition." Relevant excerpts of the 2015 deposition are attached hereto as Exhibit A. Future citations to Exhibit A are in the form (Ex. A, ___.)

[3] For the record, Plaintiffs and Ethicon agree that the opinions Dr. Blaivas proffers regarding one TVT device is often equally applicable to others in the TVT device family. (*See e.g.*, Eth. Br., 1, n.1)("Because most of Dr. Blaivas's opinions about the TVT devices are the same, citations in this brief [i.e. the Ethicon brief] are generally limited to his TVT Report.").

[4] Relevant excerpts of the 2016 deposition are attached hereto as Exhibit B. Future citations to Exhibit B will be in the form (Ex. B, ___.)

> opinions reflected in this expert report on the incidence of individual complications and the overall complication rate?
>
> A. Well, of course. That's what this paper is.[5]
>
> Q. And this information wasn't available to you and you had not done this analysis at the time of Mrs. Huskey's trial, correct?
>
> A. Correct.
>
> Q. . . . . Can you tell me why you can be certain about complication rates in August of 2015 when you couldn't be certain about complication rates in the summer of 2014?
>
> A. Because we did such an exhaustive search of the literature and this is our best estimate of the minimum complication rate. I emphasize that.

(Ex. B, 69:22-70:11; 70:17-24.)

It is critical to note that the "paper" Dr. Blaivas referenced in the above testimony as supporting his opinions at his 2016 deposition was precisely the same journal article he co-authored and that he used to support his opinions at the 2015 deposition. (*See e.g.*, Ex. A, 114:7; Ex. B, 16:18-37:5.) Ethicon relied on old testimony from the Huskey trial to argue that Dr. Blaivas could not support his opinions regarding complication rates instead of the more up-to-date testimony Dr. Blaivas originally proffered at his 2015 deposition. (Eth. Br., 3-4.) It would be manifestly unjust for Dr. Blaivas's opinions to be excluded on the basis of his 2014 *Huskey* testimony when he clearly provides adequate support for them now (and, indeed, did so at the 2015 deposition). Plaintiffs respectfully submit that the Court reconsider its opinion to the contrary. *In re Ethicon, Inc.*, 2016 WL 4500767 at *4 (the Court excluding Dr. Blaivas's complication rate opinions in Wave 1 based

[5] Dr. Blaivas is referencing a 2015 review, "Safety Considerations for Synthetic Sling Surgery," he and his colleagues authored in the scientific journal *Nature Reviews Urology* ("review article") that provides much of the scientific support for his safety and efficacy rate opinions. (*See* Blaivas, Jerry G. et. al. "Safety Considerations for Synthetic Sling Surgery." *Nature Reviews Urology* 12.9 (2015) 481-509.)

on his 2014 *Huskey* testimony). *See Pac. Ins. Co.*, 148 F.3 at 403 (motions for reconsideration may be granted to correct manifest injustice).

In addition, Ethicon also misled the Court regarding Dr. Blaivas's efficacy rate and safety rate opinions. For example, in the Ethicon Brief, Defendant argued that Table 1 in Dr. Blaivas's *Nature* review paper evidenced cherry-picking of data. (Eth. Br., 5-6.) Among other things, Ethicon argued that in choosing eleven long-term studies to include in Table 1 of his paper, Dr. Blaivas ignored ten others with rates ostensibly more favorable to Ethicon's position. (*See* Eth. Br., 5.) Ethicon is in error as no unfair choosing of data took place. And Dr. Blaivas certainly never testified to the contrary. Indeed, when questioned at the 2015 deposition, Dr. Blaivas never admitted that he excluded data and never testified that he and his colleagues erred in excluding data, notwithstanding Ethicon's arguments to the contrary. (Eth. Br., 5-6.) (*See also* Ex. A, 108:10-19)(Dr. Blaivas testifying that he did not think studies were omitted from Table 1 but planned to confirm that was the case; (*Id*., 108:21-109:6 [Dr. Blaivas admitted not considering one study but only because it involved transobturator rather than midurethral slings]; and (*Id*., 111:22-24 [yet another ostensibly-omitted study did not meet Dr. Blaivas's strenuous research criteria].)

Even more crucially, Ethicon's argument presented a fundamental misunderstanding regarding Dr. Blaivas's data in Table 1, one that led it to argue erroneously to this Court that Dr. Blaivas's data was cherry-picked, failing to include some studies that were "very good" or "well done" from Table 1. (Eth. Br., 5-6.) In fact, as Dr. Blaivas testified at the 2015 deposition, and as even acknowledged by Ethicon, (*Id*., 6) Table 1 was not related to safety rates at all but only to efficacy rates, thereby making it imminently reasonable for certain irrelevant, albeit otherwise "very good" or "well done," studies ***not about efficacy*** to be excluded by Dr. Blaivas from Table 1. For example, at one point during the 2015 deposition, Dr. Blaivas testified:

> Q. Are you going to attempt to try to figure out why these ten-plus year TVT studies were left out of the table and which other ones may have been left out, too?
>
> . . .
>
> A. I've already started doing that. ***But, in context, this review is not about efficacy, [i.e. the article Ethicon was showing Dr. Blaivas], it's about complications.*** So there wouldn't - - this - - neither of these papers, as far as I'm concerned, adds very much to our understanding of the incidence and consequence of complications.

(Ex. A, 199:10-200:1.) (emphasis added.)

Dr. Blaivas further clarified his position when he testified at the 2016 deposition. Regarding Table 1, he stated once again that Table 1 concerned efficacy rates and not safety. (Ex. B, 73:4-76:28) (*see also* Ex. B, 29:10-31:5; 58:13-59:13). Dr. Blaivas also made it clear that he utilized research techniques designed to capture all of the relevant scientific literature in drafting the review article (*id*., 22:10-24:1) (*see also* 24:6-25:3) and that simply because a study was not relevant to, and therefore was not made part of Table 1, did not mean that it was not otherwise used in Dr. Blaivas's review article (or that it did not provide any support for some of his opinions):

> Q. So you can't say that simply because something isn't on Table 1 that you didn't rely on it, use it, conclude anything about it or consider it as part of your safety considerations and complication considerations; is that right?
>
> A. To the contrary; we would have used it.

(Ex. B, 30:21-31:5.)

Notwithstanding Ethicon's argument, and certainly notwithstanding its frankly false assertion that Dr. Blaivas admitted during the 2015 deposition that he and his colleagues committed "error" in omitting some reports from their study,[6] (Eth. Br., 6.) Dr. Blaivas admitted no such error, his data

[6] Ethicon's assertion is without basis. In fact, in the deposition testimony Ethicon cites in support, Dr. Blaivas either testified 1) that he did not know if certain studies were omitted from his research (*see e.g.*, Ex. A, 193:23-194:2), 2) that data was not used because patients were lost to follow up (*id*., 325:17-340:3), 3) that some studies were not able to withstand Dr. Blaivas's rigorous methodology and, therefore excluded on that basis (*id.*, 372:18-373:2), and 4)

was not cherry-picked, and his opinions on safety and efficacy rates of TVT devices was adequately supported. Ethicon's arguments were based on false premises which led the Court to issue the Order excluding Dr. Blaivas's opinions. *See In re Ethicon, Inc.*, 2016 WL 4500767 at *4. This creates precisely the situation contemplated by applicable case law where a court's decision should be reconsidered in order to correct a manifest injustice. *See Pac. Ins. Co.*, 148 F.3d 403. Therefore, Plaintiffs now move this Court to reconsider its exclusion of Dr. Blaivas's safety and efficacy rate opinions.

B. DR. BLAIVAS HAS NOW SUPPLEMENTED HIS REPORT AND THERE IS NEW EVIDENCE TO SUPPORT HIS OPINIONS

Dr. Blaivas supplemented his expert report pursuant to Rule 26(e)(2) and served it October 17, 2016.[7] The Supplemental Report provides additional support for Dr. Blaivas's opinions, grounded in the most recent scientific literature. To the extent that this Court's Order excluding several of Dr. Blaivas's opinions is based upon a finding that they lacked support, Plaintiffs now move that the Supplemental Report provides new evidence, sufficient to justify this Court's reconsideration of its earlier opinion. *See Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d at 403 (the 4th Circuit finding that a showing of new evidence not previously available serves as one reason for a court to reconsider an earlier order.). Plaintiffs note for the record that the data in the Supplemental Report was not previously available. *See Id*. ("[I]f a party relies on newly discovered evidence in its Rule 59(e) motion, the party 'must produce a legitimate justification for not presenting the evidence during the earlier proceeding.'")(citing to and quoting from *Small v. Hunt*, 98 F.3d 789, 798 (4th Cir. 1996)(some internal quotations omitted.).

---

that some studies were not related to efficacy and, therefore, irrelevant to his review article, and particularly to Table 1. (*Id*., 199:7-17.)

[7] The Supplemental Rule 26 Report of [Dr. Blaivas] ("Supplemental Report") is attached hereto as Exhibit C. Future citations to Exhibit C will be in the form (Ex. C, ___.)

Additionally, and as argued previously regarding Dr. Blaivas's safety and efficacy rate opinions, Plaintiffs also move that the Court now reconsider its earlier Order excluding many of his opinions because manifest injustice will otherwise result. *Id*., (the 4th Circuit holding that a court may reconsider an earlier opinion in order to prevent manifest injustice.). The women in Wave 1 of this litigation will be deprived of Dr. Blaivas's reliable expert medical opinions if the Court does not reconsider its opinion. Dr. Blaivas is one of the foremost experts in the field of urogynecology in the world and his expert medical opinions regarding TVT devices, implant techniques, and medical consequences to the women who receive them will undoubtedly assist the jury. With due respect to the Court's earlier Order, Plaintiffs move that the Court reconsider its earlier opinion in light of the Supplemental Report and find that Dr. Blaivas's opinions are admissible under the standards established by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny.

In particular, the Supplemental Report provides additional scientific support for Dr. Blaivas's following opinions:

- that the TVT devices lead to serious, life-altering complications; (Ex. C, 1)(citing to a 2016 article noting that "'certain complications from MUS surgery are unique to the use of polypropylene mesh. These can include mesh exposure, chronic pelvic pain, and dyspareunia, which are the most common, as well as mesh contracture, organ perforation, and/or neuromuscular injury. Other complications may include *de novo* urgency and/or urinary incontinence (UUI), urinary tract infection (UTI), and/or urinary obstruction);'" (quoting Timbrook, Brown, et al., Evaluation and Management of Mid-Urethral Sling Complications, Curr. Bladder Dysfunct. Rep., 2016 April 18:1-9.)

- that the complication rates associated with MUS reported in recent medical literature are consistent with the complication rates Dr. Blaivas has noted in his expert report all along; (*id*)(citing again to the Brown article which found rates of complications from MUS to be "quite high," and certainly higher than the rates from the TOMUS trials that Ethicon relies upon. The Brown article concluded that overall complication rates are higher than originally reported, possibly because patients are lost to follow-up)

- that the Brown article also provides support for Dr. Blaivas's opinions that mesh surgeries result in post-operative complications that can be difficult to manage; (*id*.)

- that dyspareunia and pain can last beyond the post-operative period and may not be cured by explant or revision; (*id*)(quoting the Brown article) ("'Vaginal and/or pelvic pain, associated with or without dyspareunia, can be a quite difficult clinical presentation to evaluate and manage . . . Unfortunately MUS excision may not be curative and debilitating pain can still result.'")

- that pubovaginal slings are safe and effective alternatives to TVT; (*id*)(citing Medina CA, et al., Evaluation and surgery for stress urinary incontinence: A FIGO working group report, Neurourol. Urodyn., 2016 Mar 7); Bang, et al., Autologous pubovaginal slings: back to the future or a lost art? Research and Reports in Urology, 18 Jan 2016, Vol. 216:8, pg. 11-20; and Foss et al., Reoperation for urinary incontinence: a nationwide cohort study, 1998-2007, Am. J. Obstet. Gynecol, Feb. 2016; Mock, et al., Contemporary Comparison between Retropubic Midurethral Sling and Autologous Pubovaginal Sling for Stress Urinary Incontinence after the FDA Advisory Notification, Urology 2015; 85: 321-325;)

- that the polypropylene mesh comprising Ethicon's TVT devices cause chronic inflammation and degrade *in vivo*; (*id*, 3-4)(citing Nolfi AL, et al., Host Response to Synthetic Mesh in Women with Mesh Complications, Am. J. Obstet. Gynecol 2016; 215:206.e1-8; Imel, Adam, et. al., *in vivo* oxidative degradation of polypropylene pelvic mesh, Biomaterials 73 (2015) 131-141, 10.1016/j.biomaterials.2015.09.015.)

- that newly published animal studies likewise support Dr. Blaivas's opinions; and (*id*, 4)(citing Brown et al., Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque, Am. J. Obstet. Gynecol (2015), doi: 10.1016/j.ajog.2015.08.002.)

- that recent studies of excised meshes showed that degradation can be detected by conventional light microscopy. (citing Iakovlev V., et al., Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. J. Biomed Mater. Res. Part B 2015:00B:000.)

IV. CONCLUSION

For reasons of the foregoing, Plaintiffs move that this Court reconsider its Order of August 26, 2016 and Dr. Blaivas's expert opinions be admitted in full in Wave 1 of this litigation.

Respectfully submitted,

Date: November 3, 2016

By: /s/ Fidelma L. Fitzpatrick

Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Co-Lead Counsel MDL 2325

CERTIFICATE OF SERVICE

I hereby certify that on November 3, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/Fidelma L. Fitzpatrick
Fidelma L. Fitzpatrick
Motley Rice LLC
321 South Main Street
Providence, RI 02903
Phone: (401) 457-7700
Fax: (401) 457-7708
ffitzpatrick@motleyrice.com

Fred Thompson, III
Motley Rice LLC
28 Bridgeside Blvd.
Mount Pleasant, SC 29464
Phone: (843) 216-9000
Fax: (843) 216-9450
fthompson@motleyrice.com

Co-Lead Counsel MDL 2325